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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,508	/728,508 12/05/2003		Lavinia C. Popescu	02.36US	9085
23487	7590	09/08/2005		EXAMINER	
		ER COS, INC	KOSSON, ROSANNE		
125 PINELAWN ROAD MELVILLE, NY 11747				ART UNIT	PAPER NUMBER
MELVILLE	, NI 117	141	1653	1653	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/728,508	POPESCU ET AL.				
Office Action Summary	Examiner	Art Unit				
	Rosanne Kosson	1653				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from a, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. (D. (35 U.S.C. § 133).				
Status						
1) ☐ Responsive to communication(s) filed on 19 A 2a) ☐ This action is FINAL. 2b) ☐ This 3) ☐ Since this application is in condition for alloware closed in accordance with the practice under B	s action is non-final.  nce except for formal matters, pro					
Disposition of Claims						
<ul> <li>4)  Claim(s) 1-20 is/are pending in the application 4a) Of the above claim(s) 19 and 20 is/are with 5) Claim(s) is/are allowed.</li> <li>6) Claim(s) 1-18 is/are rejected.</li> <li>7) Claim(s) is/are objected to.</li> <li>8) Claim(s) are subject to restriction and/or</li> </ul>	ndrawn from consideration.					
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11.	epted or b) objected to by the drawing(s) be held in abeyance. Se tion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119	·					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:					

## **DETAILED ACTION**

Applicants' remarks filed on August 11, 2005 has been received. No claims have been amended, canceled or added. Accordingly, claims 1-18 are examined on the merits herewith. Claims 19 and 20 remain withdrawn as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

## Claim Rejections - 35 USC § 103

Claims 1-4, 6-13 and 15-18 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Richardson et al. (U.S. 5,490,980) in view of Green et al. (US 5,525,336); Kanebo Ltd. (JP 02-204407, see English abstract); Dane, Hair Chemistry 1, The Trichological Society, www.hairscientists.org/hair-chemistry.htm, ©2000, printed from the Internet on July 26, 2004, and the record for transglutaminase from BRENDA, <a href="http://www.brenda.uni-koeln.de/php/result\_flat.php4?ecno=2.3.2.13">http://www.brenda.uni-koeln.de/php/result\_flat.php4?ecno=2.3.2.13</a>, printed July 26, 2004. This rejection was discussed in the previous Office action.

All of Applicants' arguments have been considered, but they are not persuasive of error. Applicants assert that Richardson et al. has not been interpreted correctly because the reference discloses applying a composition comprising transglutaminase and an alkylamine to hair, because it does not disclose cross-linking of hair, because it discloses that the transglutaminase can bind the alkylamine compound to hair and because it discloses conditioning hair. In reply, Applicants have read the reference too

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narrowly, particularly as the rejection is a combination of the teachings of the cited references. Richardson et al. disclose applying a composition comprising an effective amount of transglutaminase to hair. Although the composition comprises other compounds, nothing in the composition, or in the process of applying the composition to hair, restricts the enzyme to reacting only with the alkylamine compound or compounds. The enzyme acts on both the alkylamine-containing compound(s) and on hair. Alkylamine groups in the other compound(s) and lysine residues in keratin molecules are bound to glutamine residues. It is clear from the previous Office action that BRENDA was cited because it teaches the transglutaminase reaction between lysine and glutamine residues. To provide an example of a reference in BRENDA that teaches that transglutaminase can cross-link keratin, multiple pages refer to reference no. 8, the citation of which appears on p. 29, Puszkin et al. ("Catalytic properties of a calmodulin-regulated transglutaminase from human platelet and chicken gizzard," J Biol Chem 260(29):16012-16020, 1985). Puszkin et al. disclose that transglutaminases catalyze the covalent cross-linking of glutamine-lysine bonds in proteins. Transglutaminases from hair follicles and epidermal cells have been postulated to cross-link keratin (see p. 16012).

Regarding Green et al., it is clear in the previous Office action that Green et al. were cited because they teach that transglutaminase is a cross-linking agent that cross-links cornecyte proteins that are present in the stratum corneum of the skin, hair or nails (see col. 3, lines 37-47). Green teaches that transglutaminase alone may be

applied to hair and that it cross-links hair. It is clear that Green et al. were not cited for the specific compounds that they disclose.

Regarding Kanebo Ltd., the abstract discloses that "The TGase catalyzes the reaction of free glutamine residue and lysine residue existing in the outermost layer of the hair to form a crosslinking consisting of  $\epsilon$ -(y-glutamine)lysine bond. Accordingly, the surface structure is densified, the damaged hair, the water-retainability and the moisture-retainability of hair are improved and the hair is imparted with gloss, softness and springiness." Thus, Kanebo teaches the application of transglutaminase to hair to cross-link it. Springiness is curl; straight hair is not springy. Applicants assert that water retention is not the purpose of the instant invention. But water retention occurs during conditioning, which is a moisturizing treatment, and which is the subject of withdrawn claim 19.

Regarding Dane, Applicants assert that Dane teaches that all types of bonds in hair, except for disulfide bonds, are easily defeated by external forces such as water and humidity. Applicants also assert that Dane does not teach that cross-linking of keratin shafts would be effective in maintaining and imparting curl. In reply, Dane discusses disulfide bonds, ionic bonds and hydrogen bonds and teaches that disulfide bonds are broken and rearranged to perm hair. Ionic bonds and hydrogen bonds are broken when the hair is wetted, reform when the hair is dried, and may be used to change the shape of hairs by rolling it wet and blowing it dry. Dane does not discuss covalent bonds. But, it is clear in the previous Office action that Dane was cited because he or she teaches that hair is permed by applying a cross-linking agent to

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create a new pattern, curly. One of ordinary skill in the art at the time that the invention was made would have been motivated to design a product to maintain or enhance the curl of permed hair that contains an ingredient that can cross-link keratin, as disclosed by Richardson et al., Green et al., Kanebo or BRENDA, to maintain the new crosslinking pattern in permed hair because Dane teaches that artificial curls can be created by cross-linking hair. Applicants assert that Dane renders completely unexpected and surprising the observation that a non-disulfide bond would have any ability to curl hair. But that Dane does not discuss bonds between lysine and glutamine residues has nothing to do with whether or not this observation is unexpected or surprising. Moreover, because several references do disclose that transglutaminase can cross-link hair (BRENDA, Puszkin et al. and Kanebo), this observation is not unexpected or surprising. Cross-linking amino acid residues in a strand of keratin or between strands. of keratin changes the shape of the strands by folding, compacting or coiling them. It is the cross-linking that changes the shape of the strands, not the linkage of cysteine residues versus glutamine and lysine residues.

Applicants assert that none of references even remotely suggests the desirability of cross-linking lysine and glutamine residues in hair or that transglutaminase can retain or impart curl to hair. In reply, as discussed above, Richardson et al., Green et al., Kanebo and BRENDA, teach that transglutaminase can cross-link glutamine and lysine residues in hair. Kanebo specifically mentions that hair with cross-linked glutamine and lysine residues is springier, i.e., curlier. Dane teaches that hair can be permed by cross-linking other amino acid residues. In view of these teachings, one of ordinary skill

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in the art, or anyone at all, would have recognized that it is desirable to cross-link glutamine and lysine residues in hair if he or she wanted curlier hair.

Regarding E-Z Permanent Makeup, Applicants assert that the reference does not teach that permed eyelashes are the result of cross-linked keratin. Therefore, this document cannot be connected to any other document that discusses cross-linking keratin. Applicants point to a statement that says that this product should not be confused with any product used on hair. Therefore, the references cannot be combined to suggest that transglutaminase can be used to impart curl to or retain curl in eyelashes. In reply, all the hair on the body is made of keratin, and Applicants do not assert that eyelashes are made of a different protein or material. Because eyelashes are made of keratin, they can also be permed and curled, like head hair. The purpose of the statement that the eyelash product should not be confused with products for head hair is to let the user know that the two types of products are different formulations. The eyes are much more sensitive and delicate than the scalp, and a product for use in the eye area has to be formulated differently than one applied to the scalp. Applying a hair product around the eyes is dangerous, and applying a product for the eyes to the scalp may not be effective. It is clear in the previous Office action that this reference was cited for its disclosure that eyelashes can be permed, similarly to head hair, not for its disclosure of specific ingredients. As previously discussed, in looking for a composition that can maintain or enhance the curl of eyelashes, one of ordinary skill in the art would have been motivated to use or adapt

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an enzyme that can maintain or enhance curl in hair. The references cited above disclose that transglutaminase can maintain or enhance the curl of hair.

In view of the foregoing, the rejections of record are maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Rosanne Kosson Examiner Art Unit 1653

rk/2005-09-01

ROBERT A. WAX
PRIMARY EXAMINER